North Carolina
Lab-Oratory
N.C. Department of Health and Human Services / State Laboratory of Public Health

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Lab-Oratory, Spring 2010 **Number 96**

From the Director's Chair

Leslie A. Wolf, PhD, HCLD (ABB)
Laboratory Director

I hope this issue of LabOratory finds all of you looking forward to spring! We are excited because the construction phase of the new facility housing the State Laboratory of Public Health and the Office of the Chief Medical Examiner begins. To address frequently asked questions and to provide the history of this success story, we have organized the answers in a journalistic manner.

What: North Carolina Department of Health & Human Services has contracted to build a new 220,000 square foot facility in west Raleigh to house the North Carolina State Public Health Laboratory (NCSLPH) and the Office of Chief Medical Examiner (OCME).

Who: BE&K, a subsidiary of KBR of Houston, Texas, will be the general contractor. O'Brien/Atkins Associates PA of Durham is the project's architect, with laboratory planning and consultation provided by HDR/CUH2A. The contract award is $52 million.

When: The building project has been in the planning stages since 2004 when a feasibility study was conducted, and following approval by the NC General Assembly,

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MISSION statement

The State Laboratory of Public Health provides certain medical and environmental laboratory services (testing, consultation and training) to public and private health provider organizations responsible for the promotion, protection and assurance of the health of North Carolina citizens.

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bonds for the project were sold in 2006. The building contract began Feb. 8, 2010, and groundbreaking is anticipated to occur in April 2010. Construction is anticipated to be completed in February 2012.

Where: The new building will be located near the northeast corner of the intersection of Edwards Mill Road and Wade Avenue across from the RBC Center arena and near the North Carolina National Guard's new joint forces headquarters and emergency operations center that is under construction. The address will be on District Drive.

Why: The Bath Building was commissioned in October 1973 and has 120,000 square feet. That same year, the OCME moved into two floors of a laboratory building on the campus of UNC Medical School and Hospital complex. The new facility will replace the state's existing, 37-year-old laboratory in the Bath Building in downtown Raleigh for SLPH. The OCME is located in the Brinkhous-Bullitt Building, a 37-year-old building on the University of North Carolina at Chapel Hill campus. The current facilities no longer accommodate the sophisticated equipment, sample processing and staff needed to process the volume of laboratory testing and autopsies required by the state.

How: Following approval by General Assembly, the new facility was funded through sale of Certificates of Participation (bonds) in 2006. The State Health Director at this time, Dr. Leah Devlin, understood that the laboratory's role in high profile testing during numerous public health crises, as well as the critical role that the OCME played in death investigations, and gained the attention of several key NC senators and representatives. Multiple laboratory tours pointed to the disadvantages and challenges of performing state of the art testing and other examinations in a 37-year-old building. The concurrent need for a new OCME facility made a compelling case for a co-located building. In 2006, a small group of NC legislators, the DHHS Secretary and Deputy Secretary, the State Health Director, the Chief Medical Examiner and State Public Health Laboratory Director subsequently toured the new state of the art Virginia state laboratory and new Chief Medical Examiner facilities. The similarity of the needs of the populace in the two states together with the strong contrast between the two state's facilities built strong support for a new NCSLPH and OCME.

Submitted by:
Leslie A. Wolf, PhD, Laboratory Director, NCSLPH

Newborn Screening: A Test to Save a Baby's Life

Newborn screening is a comprehensive blood test to screen newborns for genetic and metabolic disorders. Since symptoms are not always obvious at birth, newborn screening provides a way to detect serious health problems before the infant becomes ill. Early diagnosis and treatment of the disorders on North Carolina's newborn screening panel can prevent mental retardation, serious physical disabilities or even death.

A few drops of blood are collected from the baby's heel before the baby leaves the hospital nursery. The blood specimen is then sent to the North Carolina State Laboratory of Public Health for testing. When the screening results are indicative of a possible disorder, the health care provider is notified and repeat testing and/or follow-up testing will be performed. The baby can be referred to a specialist for diagnostic testing and further care.

North Carolina began its newborn screening program in 1966 by testing for a single disorder, Phenylketonuria (PKU). With the implementation of tandem mass spectrometry in 1997 and DNA-based technologies in early 2009, the State Lab currently screens newborns for more than thirty (30) disorders. The disorders (See "List of Disorders" on page 5) include galacto-semia, primary hypothyroidism, congenital adrenal hyperplasia (CAH), hemoglobinopathies, biotinidase deficiency, cystic fibrosis, amino acid metabolism disorders (7 disorders), fatty acid oxidation disorders (10 disorders) and organic acidurias (8 disorders).

In 2008, the lab screened 130,758 newborns and identified 231 newborns with disorders. The most common disorders detected are sickle cell diseases (121), followed by primary hypothyroidism (65), medium chain

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Newborn Screening cont. from page 2

acyl coenzyme A dehydrogenase deficiency (MCADD, 10) and pheylketonuria/hyperphylalaninemia (PKU/HPA, 8). These statistics have remained fairly constant through the years, although North Carolina's newborn population has greatly increased over the past five years. Cystic Fibrosis (CF), which is estimated to have about 30 cases per year, was not included in these statistics since CF screening did not begin until April 2009.

Although the NC State Laboratory of Public Health continuously strives to improve the laboratory technologies used in this program, newborn screening is not a definitive diagnostic test. Health care providers as well as parents should be aware that if a baby develops symptoms suggestive of one of these disorders, the newborn should be further evaluated, even if the newborn screen was normal.

Newborn screening is more than laboratory screening. Follow-up is also an important component of this program. The follow-up services are provided by the Children and Youth Branch and the NC Sickle Cell Syndrome Program in the Division of Public Health and by the University of North Carolina School of Medicine. Through a close partnership between lab and follow-up staff, North Carolina's newborns are assured of a good opportunity for a healthy start in life.

Submitted by:
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NC State Laboratory of Public Health

Assistance Available for Newborn Screening Issues

Do you encounter frequent questions from staff about collecting newborn screening specimens? Are you unsure how to correctly fill out the form? Is your facility receiving numerous lab reports stating that newborn specimens are unsatisfactory?

These questions and more can now be addressed by the NC State Laboratory of Public Health's (NCSLPH) Newborn Screening Consultant, a position that is new to the NCSLPH's Newborn Screening Laboratory. This position was filled in June 2009 by Ann Grush, former supervisor of the laboratories screening for congenital adrenal hyperplasia, congenital hypothyroidism, galactosemia and biotinidase deficiency. Ann has been a part of the Newborn Screening Program since 1980. She began her career as a technician in the RIA and PKU Labs and assumed a supervisory role in 1987. This experience makes her well qualified to offer assistance to clients with questions and issues concerning the newborn screening process.

The primary goals of the new consultant position will be to:

- Educate submitters and healthcare providers about the Newborn Screening Program, with emphasis on specimen collection, newborn screening disorders and reporting;
- Strengthen and advance the quality of North Carolina's Newborn Screening Program, with emphasis on reducing the number and type of unsatisfactory specimens and other quality assurance issues; and
- Facilitate communication between the Newborn Screening Program and its clients.

Submitters and healthcare providers are encouraged to view this position as a valuable resource for getting questions answered and issues resolved concerning the screening process. Ann may be contacted by phone at 919-807-8881 or by e-mail at ann.grush@dhhs.nc.gov.

Many of your questions concerning specimen collection and form completion may also be answered by accessing the on-line form training available on the State Lab website at *http://slph.ncpublichealth.com/*. Click on Form Training under the Newborn Screening tab on the right side of the home page. After completing the training, participants may take a quiz to receive 1.5 contact hours of continuing education credit.

Please take advantage of both of these resources to ensure North Carolina's newborns have the best care possible!

Submitted by:
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Supervisor, Hemoglobinopathy/
Cystic Fibrosis Laboratories

5th Annual North Carolina Clinical Laboratory Day

On Oct. 9, the NC State Laboratory of Public Health's Laboratory Improvement Unit presented our 5th annual Clinical Laboratory Day. This year's event, titled "The Four Cornerstones of World-Class Phlebotomy", was co-sponsored by the Texas Health Institute and featured Dennis Ernst, who was the speaker for our 1st Clinical Lab Day in 2004. The event was attended by laboratorians, nurses, educations and students from throughout North Carolina.

Dennis J. Ernst MT(ASCP) is the director of the Center for Phlebotomy Education, Inc. in Corydon, Indiana. Besides being a highly recruited international lecturer, he has authored over 50 articles on phlebotomy, two textbooks and a reference book containing answers to hundreds of specimen collection questions. He chairs the CLSI working groups that write the standards for specimen collection, is a member of MLO magazine's "Tips From the Clinical Experts" panel, and the editor of the *Phlebotomy Today* family of newsletters, read monthly by over 10,000 subscribers worldwide.

Mr Ernst divided the day into the four cornerstones of World-Class Phlebotomy: Preventing Preanalytical Errors; Exposure Prevention; Customer Service Check-Up and Protecting Yourself from Phlebotomy-Related Lawsuits.

Using information based on the latest CLSI standards and guidelines the *Preventing Preanalytical Errors* presentation discussed errors that can alter test results during blood specimen collection, transportation and storage.

The second cornerstone: *The Exposure Prevention* presentation used a self-assessment exercise to let phlebotomists and those who manage them know how safe they and their staff are from bloodborne exposures.

With an emphasis on telephone etiquette, Mr. Ernst discussed behaviors that reflect and detract from professionalism, in his *Customer Service Check-Up*. The presentation concluded with a discussion on how managers can inspire a culture of customer service excellence.

In the 4th cornerstone, Mr. Ernst ended our day outlining policies, procedures and practices that phlebotomists and their managers can implement to minimize the risk of litigation. *Protecting Yourself From Phlebotomy-Related Lawsuits* identified common errors in the performance of venipunctures that cause minor and catastrophic injuries to patients.

Event participants were able to gather information, watch product demonstrations, and take home samples from the program's 10 corporate sponsors:, Beckman Coulter, The Center for Phlebotomy Education, Fisher Scientific, Hemocue, Laboratory Supply Company, Medical Laboratory Observer, Olympus America, Sarstedt and VWR International, Inc. Our event would not have been possible without their generous support.

Newborn Screening Laboratory: List of disorders

November 10, 2009

Disorders detected by tandem mass spectrometry (MS/MS)

Amino Acid disorders

Argininosuccinic aciduria (ASA)

Citrullinemia (CIT I)

Homocystinuria (cystathionine beta synthase) (HCY)

Maple syrup urine disease / branched-chain ketoacid dehydrogenase (MSUD)

Phenylketonuria / hyperphenylalaninemia (PKU)

Tyrosinemia type II (TYR-II)

Tyrosinemia type III (TYR-III)*

Organic Acid Disorders

Glutaric acidemia type I (GA-I)

Multiple carboxylase deficiency (MCD) *

3-Hydroxy-3-methylglutaryl-CoA lyase deficiency (HMG) *

Isobutyryl-CoA dehydrogenase deficiency (IBD)

Isovaleric acidemia / isovaleryl-CoA dehydrogenase (IVA)

Beta-ketothiolase (BKT) / short-chain keto acylthiolase deficiency (SKAT)

Methylmalonic aciduria (MMA) See Notes

2-Methylbutyryl-CoA dehydrogenase deficiency (2-MBD)

3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC)

Propionic acidemia (PPA, PROP)

Fatty Acid Disorders

Carnitine/acylcarnitine translocase deficiency (CAT) *

Carnitine palmitoyltransferase II deficiency (CPT II)

Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)

Multiple acyl-CoA dehydrogenase deficiency (GA-II)

Long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD)

Short-chain acyl-CoA dehydrogenase deficiency (SCAD)

Trifunctional protein deficiency (TFP)

Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD)

* no cases yet detected by North Carolina Newborn Screening Laboratory.

Disorders detected by biochemical and other technologies

Biotinidase deficiency (BIO)

Congenital adrenal hyperplasia (CAH)

Galactosemia/ galactose-1-phosphate uridyl transferase deficiency (GALT)

Primary congenital hypothyroidism (CH)

Hemoglobin C disease (FC)

Hemoglobin E disease (FE)

Sickle cell disease (FS, HB S/S)

Sickle/hemoglobin C disease (FSC, HB S/C)

Sickle/hemoglobin E disease (FSE, HB S/E)

Cystic Fibrosis (CF)

Notes:

Methylmalonic Acidemia (MMA) includes:

Methylmalonic Acidemia (Methylmalonyl-CoA mutase) (MUT)

Methylmalonic Acidemia (Vitamin B12 Disorders) (CBLA,B)

Methylmalonic Acidemia (CBL C,D)

Methylmalonic Acidemia (MMA) includes:

Methylmalonic Acidemia (Methylmalonyl-CoA mutase) (MUT)

Methylmalonic Acidemia (Vitamin B12 Disorders) (CBLA,B)

Methylmalonic Acidemia (CBL C,D)

ASCP BOR and NCA Form Single Certification Agency

July 22, 2009

(Chicago) – The American Society for Clinical Pathology Board of Registry (BOR) and the National Credentialing Agency for Laboratory Personnel (NCA) on July 21, 2009, signed an agreement forming a single certification agency for medical laboratory professionals. The agency will be called the ASCP Board of Certification (BOC). The agreement is effective on Friday, Oct. 23, 2009. At that time, the NCA will be dissolved as a corporation.

Kathleen Becan-McBride, MT(ASCP)^{CM}, BOR Chair, and Susan Morris, CLS (NCA), NCA President, announced the agreement at the 2009 Annual Meeting of the American Society for Clinical Laboratory Science (ASCLS) this week in Chicago.

"Unity in the clinical laboratory profession will bring more recognition and respect from the public and other healthcare professions," said Ms. Becan-McBride. "We will increase our credibility when advocating for the profession on legislative and regulatory issues that impact our practice."

Ms. Morris said that a single credential and single standard of qualification will simplify entry into the profession for new graduates. "Likewise, employers will find it easier to set standards for entry level competency that will ensure patient safety," she added.

ASCP BOR Executive Director E. Blair Holladay, PhD, SCT(ASCP)^{CM}, commended the work of the negotiation teams, examination committees, and the participating organizations' boards and staff.

"This process to achieve a single certification agency took four years and involved many hours of negotiation, consideration of many different models, careful deliberation and due diligence, and a determination to make this work for the profession," Dr. Holladay added.

"We knew going into these discussions that it would take time, leadership and great care to create a new, unified Board of Certification that combined the best of both certification organizations," Ms. Morris said.

Sheila O'Neal, NCA Executive Director, said that much of the negotiation process work focused on creating a newly reorganized board structure and composition, and on resolving variances in policies between the two organizations. "None of that could be announced before now because we have been busy coming to agreement," she said. "Now we will roll up our sleeves and start the operational work."

The BOC Board of Governors will be composed of five ASCP Fellows (pathologists), five ASCP laboratory professionals, four representatives of ASCLS, two representatives of the Association of Genetic Technologists, eight representatives from the eight participating societies respectively, and one public representative.

The "ASCP" suffix will be attached to all BOC certifications. Current and active certifications will be transferred to the ASCP BOC; no examination will be required for the transfer. Medical technologists (MT) and clinical laboratory scientists (CLS) will be called Medical Laboratory Scientists (MLS). The designation will be MLS(ASCP).

More information and answers to frequently asked questions about the ASCP Board of Certification will be posted at *www.ascp.org/bor* and *www.nca-info.org*.

Article available at *www.ascp.org/MainMenu/laboratoryprofessionals/ASCP-BOR-and-NCA-Form-Single-Certification-Agency.aspx*

An Update on Cystic Fibrosis Newborn Screening in North Carolina

Cystic fibrosis (CF) is a genetic condition that affects the lungs and digestive system. CF is caused by a genetic defect in the "CF gene," cystic fibrosis transmembrane conductance regulator (CFTR), which transports chloride across the cell membrane and regulates sodium absorption. As a result of a defective CFTR protein, the body is unable to regulate the ion balance. Mucous becomes thick and sticky and builds up in the lungs, digestive system and other organs, causing chronic respiratory, digestive and male fertility problems.

The clinical expression of CF varies greatly, even among affected members of the same family. Chronic lung infections and progressive deterioration of lung function are major causes of morbidity and mortality in people with CF. In the 1950's, most children with CF died in infancy or early childhood. Pneumonia and malnutrition were the most common causes of death. Today the median age of survival for individuals with CF is 37 years old or older. Early diagnosis and treatment leads to improved nutritional status, better growth, and fewer hospitalizations. For these reasons CF was added NC State Laboratory of Public Health's (NCSLPH) newborn screening panel in April 2009.

Genetics of Cystic Fibrosis

The CF gene is located on each of the two copies of chromosome 7. Everyone has two copies of the CF gene—one from each parent. Only one functional CF gene is necessary for proper CFTR protein function. If someone inherits one defective CF gene and one working copy they are known as a "carrier." Carriers do not have CF since they have one functional CF gene. However, when an individual has two copies of a CF gene mutation, they are affected with CF.

CF affects all races and ethnic groups; however, it occurs most often in the Caucasian population. More than 10 million Americans, and approximately one in 25 Caucasians, is a symptomless carrier of a CF gene mutation. There are over 1,000 different mutations known to occur in the CF gene. Because the various CF mutations influence the clinical presentation and severity of the disease differently, testing and counseling may be useful.

Prenatal Screening for Cystic Fibrosis

The American College of Obstetrics and Gynecology and the American College of Medical Genetics recommend that all Caucasian couples who are pregnant or considering becoming pregnant be offered carrier screening for CF and that non-Caucasian couples be made aware of the availability of carrier screening for CF. Genetic counseling is highly recommended for carrier parents and for individuals with CF. With each pregnancy, two carrier parents have a 25 percent chance of having a child with CF. Individuals with CF will pass on one of their CF gene mutations to all of their children. Partners of individuals with CF may find CF carrier testing helpful in order to determine the chance of having a child affected with CF.

Newborn Screening for Cystic Fibrosis

Most newborns with CF do not show symptoms of the disease. By screening for CF in newborns, treatment can start before symptoms occur, resulting in improved growth, maintained lung function, fewer hospitalizations, and increased life expectancy.

The North Carolina State Laboratory of Public Health (SLPH) currently uses a two-tier strategy in newborn screening for CF. The first tier involves measuring immunoreactive trypsinogen (IRT), a pancreatic protein typically elevated in infants with CF. The IRT value is abnormal when it exceeds the daily 95th percentile. This is a floating cut-off value which varies daily and by season. The second tier involves DNA testing using a panel of 46 of the most common disease-causing mutations in the CF gene. A positive, or abnormal, newborn screening result is not a diagnosis of CF, but rather is an indication for additional testing in order to rule out or confirm a diagnosis of CF. While many newborns may have an abnormal newborn screening result for CF, less than 5 percent will actually have CF. There are three possible outcomes leading to an abnormal newborn screening result for CF.

1) **Two mutations detected** – The baby most likely has CF. Sweat chloride testing at an accredited CF Center is recommended to confirm a diagnosis of CF.

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Update on Cystic Fibrosis Newborn Screening cont. from page 7

2) **One mutation detected** – The baby is probably an unaffected carrier of a CF disease-causing mutation. However, there is 1-3 percent chance that the baby has a second, rare mutation undetected by the SLPH DNA panel. Sweat chloride testing at an accredited CF Center is recommended to rule out CF.

3) **No mutations detected with ultra high IRT >99.8th percentile** – Most likely the baby will not have CF, nor be an unaffected carrier. However, there is a very small chance that the baby has two rare mutations undetected by the SLPH DNA panel. Sweat chloride testing at an accredited CF Center is recommended to rule out CF.

In all cases of an abnormal newborn screening result for CF, the NC CF Follow-Up Coordinator notifies the primary care physician of the abnormal result by telephone and fax. The physician informs the parents that a sweat chloride test at an accredited CF Center is recommended in order to rule out or confirm a diagnosis of CF. Genetic counseling is strongly recommended following a sweat chloride test.

Sweat Chloride Testing

Individuals with CF have an increased amount of chloride (salt) in their sweat. The sweat chloride test measures the concentration of salt after sweat glands are stimulated with pilocarpine iontophoresis. Sweat chloride testing is the gold standard for obtaining a diagnosis of CF. However, the sweat chloride test is not an appropriate test for determining CF carrier status.

Sweat chloride testing is difficult to perform and should be done at CF Foundation-Accredited Centers to ensure accuracy of results. For best results, infants must be at least 14 days old and 2,000 grams in weight. On the day of the sweat test, parents should avoid using lotions, creams or moisturizing soaps on the baby's arms and legs. A colorless, odorless gel known to cause sweating is applied to the skin on the arms or legs. Electrodes are applied for about five minutes to stimulate sweating. The skin may feel warm and tingly, but it is not painful. The sweat is collected on a gauze or disk and sent to a laboratory for analysis after 30 minutes. The entire sweat testing procedure lasts approximately one hour. Results are usually available on the next working day after the test is performed.

Sweat Chloride Test Results

A **negative** sweat test result (<40 mmol/L) means that a normal concentration of salt was found in the baby's sweat. A negative result rules out the diagnosis of CF. It is very rare for an individual with CF to have a negative sweat test result. No further testing is required following a negative sweat test result. Genetic counseling may be useful for interpretation of the result and explanation of carrier status.

A **positive** sweat test result (>60 mmol/L) is consistent with a diagnosis of CF. Individuals with CF will have a positive sweat chloride test from birth. Once a test result is positive, it will remain positive, even as a person grows older. A referral should be made to initiate care at a CF Center as well as to a genetic center for formal genetic counseling following a positive sweat test result.

A **borderline** result (40–60 mmol/L) is inconclusive, falling between a positive and negative result. Another sweat chloride test or genetic test is recommended following a borderline result.

Sometimes the quantity of sweat obtained is not sufficient to measure the salt concentration. This result is called **Quantity Not Sufficient** (QNS). The sweat chloride test will need to be repeated at a later date following a QNS result.

The above are current ranges for sweat test results recommended by the CF Foundation for infants and children six months of age and older. However, recent guidelines recommend using a lower limit of <29 mmol/L for normal in infants less than six months of age. Individual CF Centers and sweat testing laboratories may use different cut-off values.

The First Six Months of CF Newborn Screening in North Carolina

The newborn screening program uses a DNA panel consisting of 46 of the most common disease-causing mutations in the CF gene. The newborn screening program has thus far detected 22 of the 46 mutations on the DNA panel. The three most common mutations that have been detected include 1) Delta F508, 2) D1270N, and 3) R117H.

There were 288 abnormal CF newborn screen results that required follow-up during the first six months. The newborn screening program has identified 18 infants with a confirmed CF diagnosis. Of the 18 infants diagnosed

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Update on Cystic Fibrosis Newborn Screening cont. from page 8

with CF, 14 had two mutations detected by newborn screening and four had only one mutation detected. See Figure 1 for further breakdown of abnormal CF newborn screening results.

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Submitted by:
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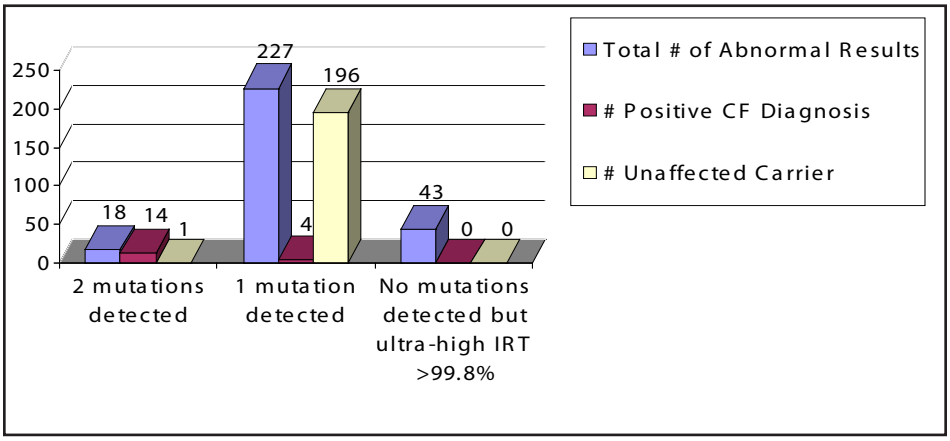
Cystic Fibrosis Follow-Up Coordinator
North Carolina Division of Public Health,
Children & Youth Branch



Note: Abnormal results still requiring confirmatory sweat chloride testing are not included in the chart. All abnormal results with no mutations detected had normal sweat test results and no further testing is recommended.

Have a CLIA question?

If so, the NC Division of Health Regulation, Acute and Home Care Licensure and Certification Section has created a web site just for you (see link below).

www.ncdhhs.gov/dhsr/ahc/clia/index.html

If you are not familiar with this site, it offers general CLIA information, including NC facts and figures, FAQs, and the NC fee schedule.

SAVE THE DATE

Carolinas Clinical Connection

April 21-23, 2010

"April in Asheville Again"
Crowne Plaza Resort
Asheville, N.C.

Contact Mary Midkiff
(mmidkiff@nhsc.org)
or Dan Southern
(southern@email.wcu.edu)
for more information.

Influenza (Flu) Testing FAQ

Q: Who can submit specimens to the North Carolina State Laboratory of Public Health (NCSLPH) to be tested for flu?

A: Currently, sentinel sites are asked to submit a limited number of specimens a week for surveillance purposes. Hospitals may submit specimens for patients in ICU or for patients whose deaths are believed to be influenza-associated.

Q: Why can't the NCSLPH test everyone with flu symptoms?

A: Testing is performed primarily to monitor the current influenza strains for surveillance purposes—to watch for genetic variations or antiviral resistance, and to know which flu strains are currently circulating in North Carolina. Testing is available at some commercial labs for patients who do not meet the criteria for testing at the NCSLPH. However, according to the Centers for Disease Control and Prevention (CDC), most people with flu symptoms do not need a test for H1N1 because the test results usually do not change how a patient is treated.

(www.cdc.gov/h1n1flu/diagnostic_testing_public_qa.htm)

Q: Isn't flu season over? Should we still be submitting specimens for flu testing?

A: While H1N1 cases have decreased, flu-associated hospitalizations and deaths are still being reported. The NCSLPH continues to have positive flu cases. It is important for sentinel sites to continue submitting specimens for surveillance purposes. For the latest influenza update, please see: **www.epi.state.nc.us/epi/gcdc/flu0910.html**.

Q: Do we need to specifically request testing for Swine Flu (H1N1 Pandemic)?

A: Any request for flu, influenza, H1N1, seasonal flu, flu A, flu B, or a respiratory panel is tested for H1N1 and seasonal flu. If flu is not detected, further testing is conducted for respiratory panel requests or if otherwise requested on the requisition form.

Q: What methods does the NCSLPH use to test for flu?

A: Routinely, most specimens are tested using a Food and Drug Administration (FDA) emergency use authorized RT-PCR assay. Some

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Influenza (Flu) Testing cont. from page 10

specimen sources are not approved for this assay and will be put into culture. Respiratory panel requests, if RT-PCR negative, are innoculated into culture to test for other respiratory viruses. Other flu requests can also include "culture if negative" to request further testing. Other RT-PCR negative specimens may be selected at random for culture for virus surveillance purposes. When testing for flu, RT-PCR is more sensitive than culture. However, other respiratory viruses may be isolated in culture, while the RT-PCR assay is designed to detect flu only.

Q: What kind of specimens can be tested for flu?

A: For RT-PCR testing, please submit upper respiratory tract specimens such as nasopharyngeal swabs, throat swabs, nasal swabs, nasal aspirates or nasal washes; or lower respiratory tract specimens such as broncheoalveolar lavage, bronchial aspirate, bronchial wash, endotracheal aspirate, endotracheal wash, tracheal aspirate, or lung tissus. Other specimens, such as sputum, are innoculated into culture.

Q: What will cause a specimen to not be tested?

A: All specimens must be kept cold in transit. Specimens for flu RT-PCR testing that are received ambient are unsatisfactory for testing and will not be tested. All specimen vials must be labeled with a first and last name and a unique numerical identifier (i.e., birth date or SS #). Improperly labeled vials or vials that do not match the requisition forms are unsatisfactory for testing and will not be tested. Specimens collected using calcium alginate swabs will not be tested.

Q: What are the requirements for shipping specimens?

A: Swabs should be placed in viral transport media (commercially produced VTM is acceptable) and shipped immediately. All specimens should be tested within 72 hours of collection. Keep specimens cold by shipping in an insulated container with ice packs. Fully complete the viral specimen submission form found at **http://slph.ncpublichealth.com/Forms/DHHS-3431.pdf**. Submitting an incomplete requisition form creates more work for the submitter and the NCSLPH and may result in delays in testing.

Q: As a sentinel site, how do we decide which specimens to submit for flu testing?

A: It's important to send specimens for patients who are sick with a flu-like illness despite having received a flu vaccine or Tamiflu (please note dates vaccinated or treated.) Patients with a travel history or those who are unusually sick are also priorities. Please do not send specimens on multiple family members who have similar symptoms.

Q: How long does it take to get results?

A: It can take up to three business days for RT-PCR results, or 14 days for culture results. Results are available online (for original submitters only) with hard copies to follow in the mail. Testing is not available on weekends or holidays.

Q: Why doesn't the NCSLPH fax results?

A: Once results are released, they are available immediately for viewing and printing online; submitters can even check to see that a specimen was received and is being tested. Submitters are notified by phone of

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Influenza (Flu) Testing cont. from page 11

all positive results. There is not enough available staff to fax results to over 100 submitters. Submitters can go to **http://slph.ncpublichealth.com** to sign up for web access.

Q: What if we have a patient who might be resistant to antiviral medication?

A: Clinicians can contact the CDC Emergency Operation Center (EOC) laboratory desk to determine whether the patient specimen may be submitted to the CDC for diagnostic antiviral resistance testing. The appropriate forms are sent after consultation with CDC. Following approval, clinicians are asked to submit directly to the CDC due to the scope of clinical information required and to decrease turnaround time. Contact CDC EOC at eoclaboratory@cdc.gov or 770-488-7100. If testing is indicated, please notify the NCSLPH.

Q: If a patient has had H1N1, do they still need to get the vaccine?

A: According to the CDC, if a patient had 2009 H1N1 flu, as confirmed by an RT-PCR test, he should have some immunity against 2009 H1N1 flu and can choose not to get the 2009 H1N1 vaccine. However, if the patient was ill but do not know for sure if it was H1N1, and/or if a physician recommends getting the vaccine, the patient should be vaccinated.

(www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm)

Q: Can we rely on rapid flu test results?

A: According to the CDC, rapid tests vary in their ability to detect flu viruses. Depending on the rapid test used, their ability to detect 2009 H1N1 flu can range from 10% to 70%. This means that some people with a 2009 H1N1 flu infection have had a negative rapid test result.

(www.cdc.gov/h1n1flu/diagnostic_testing_public_qa.htm)

Q: Does a negative flu test from the NCSLPH mean that my patient doesn't have the flu?

A: No. If there is very little virus present, it's possible that the flu virus will not be detected by RT-PCR or isolated in culture. Many circumstances affect the viral load in the patient specimen: time between onset of symptoms and specimen collection (as soon as possible); time between specimen collection and testing (should be less than 72 hours); sample collection procedures; specimen handling; etc. Treatment decisions should not be based solely on test results.

Q: Where can I find the most current information, including the latest recommendations, requirements, and epidemiological information?

A: Both NC and the CDC have websites that provide guidance for health professionals:
www.epi.state.nc.us/epi/gcdc/H1N1flu.html
www.cdc.gov/h1n1flu/clinicians

The following websites also offer additional information:

www.flu.nc.gov (general flu information)

www.cdc.gov/h1n1flu (general flu information)

www.flu.nc.gov/epi/gcdc/flu0910.html (NC flu surveillance)

www.cdc.gov/flu/weekly (US flu surveillance)

2010 WORKSHOP SCHEDULE
FOR APRIL – AUGUST

SPRING

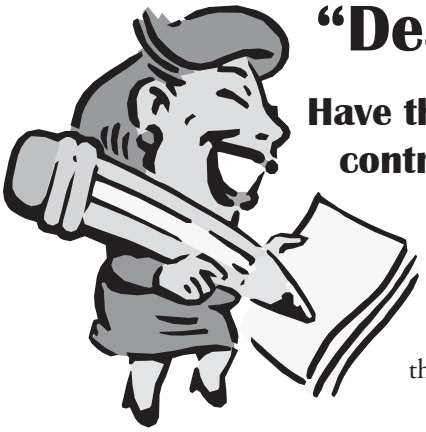
N.C. Department of Health and Human Services
State Laboratory of Public Health
Laboratory Improvement (LI)

DATE	TITLE	APPLICATION DEADLINE
April 15, 2010	Bioterrorism Preparedness for Clinical Laboratories	Mar. 15, 2010
April 28, 2010	Microscopy: Viewing & Reviewing (Advanced)	Mar. 31, 2010
April 29, 2010	Diagnosing Vaginitis Using the Wet Mount Exam	Mar. 19, 2010
May 6, 2010	Biosafety/Biosecurity: Minimizing the Risk in the Lab	Apr. 28, 2010
May 26-27, 2010	Laboratory Methods in the Diagnosis of Gonorrhea	Apr. 26, 2010
July 20-21, 2010	Microscopy: Viewing & Reviewing (Basic)	Jun. 21, 2010
July 22, 2010	Diagnosing Vaginitis Using the Wet Mount Exam	Jun. 22, 2010
Aug 3-6, 2010	Bacteriological Methods for the Analysis of Water	July 6, 2010

Disclaimer: These workshops are not intended to replace formal education but to enhance skills and promote use of recommended standard techniques.

For more information, consult your LI 2010 WORKSHOP ANNOUNCEMENTS or contact LI at 919-733-7186.

http://slph.ncpublichealth.com



"Dear Lab-bey"

Have there been any changes in the requirements of quality control frequency of Gram stains for users of the BD Gram Stain Kits?

Good news is available regarding required quality control frequency for users of the BD Gram Stain kit. In the most recent version of the BD Gram Stain kit package insert dated June 2008, the requirements are:

User Quality Control:

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures.[1]

BD no longer specifies gram stain quality control must be performed daily and defers to local, state and/or federal regulations. CLIA requirements for gram stain quality control are as follows:

Sec. 493.1261 Standard: Bacteriology

(a) The laboratory must check the following for positive and negative reactivity using control organisms:

(2) Each week of use for Gram stains.[2]

What does this mean for you? Users of the BD Gram stain kit are no longer required to perform quality control with each use. Gram stain quality control can now be performed each week of use as stated in CLIA regulations.

REFERENCES:

1Becton Dickinson and Company. *BD Gram Stains Kits and Reagents Package Insert*. Revision 6/2008. "Available at: www.cdc.gov/clia/regs/subpart_k.aspx#493.1261. Accessed November 16, 2009."

2Centers for Disease Control and Prevention. *Current CLIA Regulations-Part 493-Laboratory*. "Available at: www.cdc.gov/clia/regs/subpart_k.aspx#493.1261. Accessed November 16, 2009."

Submitted by:
Tracey Shives, BS, MT (ASCP),
Regional Laboratory Consultant

"Dear Lab-bey..."

If you have a technical laboratory question that you would like to have answered please submit it to: tracey.shives@dhhs.nc.gov.

The answer to your question may be featured in the next edition of Lab-Oratory.

The Safety Corner

Properly Disposing of a Mercury Thermometer

So you've broken a thermometer and it happens to be one that contains mercury. How do you dispose of this broken glass and the mercury it contained?

- Follow all directions in the spill kit and use proper PPE
- Place the used sponge in a zippered plastic bag (NOT A BIOHAZARD BAG)
- Place broken pieces of glass in the same bag as the sponge (Handle glass with tongs, not a broom)
- Place gloves in bag last
- Seal bag
- Place the sealed bag in another plastic bag
- Place again in another plastic bag (broken thermometer and Mercury are now triple bagged
- Place bag in a sealed plastic bucket for disposal by a hazardous waste company
- Notify your supervisor and the safety officer/chemical hygiene officer
- Fill out an incident report

Clean up materials and thermometer in zip bag.

Remember:

Mercury is very toxic and vaporizes at room temperature.

Wear the proper PPE during cleanup. If you contaminate your clothing it must be disposed of and remember to avoid walking through the spill because your shoes could spread the contamination to other areas.

NEVER:

- **use a vacuum, a broom or a paintbrush**
- **use household cleaning products**
- **put Mercury or contaminated clothing in the trash**
- **put Mercury in a burn up box**
- **put Mercury or the broken pieces in a biohazard bag (Hg cannot be autoclaved)**
- **pour Mercury down the sink**

Submitted by:
Kaye Flood, Chemical Hygiene Officer
Chemical Terrorism Unit Supervisor
NC State Laboratory of Public Health

Kudos!

- Congratulations to our State Lab retirees!
  - Terry Hogg
  - Lisa Ballance
  - Lou Harwood
  - Susan Weavil
  - Lee Outlaw
  - Jake Rogers
  - Colleen Miller
  - Chris O'Connell
  - Vickie Whitaker
  - Georgena Millar
  - Brenda Nichols
  - Vicki Painter

- La'Vonda Benbow responded perfectly to an unannounced security drill on Oct. 7, 2009. She prohibited a suspicious character from entering the Bath Building. Great job La'Vonda!

- Susan Beasley, Supervisor of the Environmental Microbiology laboratory in the Environmental Sciences Unit, was selected as the Employee of the Quarter for Fall 2009.

  Susan was selected in the category of Leadership. She demonstrates dedication to her laboratory and her staff by working side by side with her team, willing to do any task herself that she asks them to do. Susan's laboratory must meet standards for both FDA and EPA regulations, and under her leadership, the Environmental Microbiology laboratory has been successful in meeting these standards. As a result of numerous quality assurance checks, when laboratory results are released with Susan's name on them, they are correct. She achieves quality work and high morale within her group because of her leadership.

- Sherri Felts, Laboratory Improvement Regional Consultant (Greenville), was selected as the 2009 NC Public Health Association Laboratorian of the Year.

  Described by coworkers as "manna from heaven" when she first joined Laboratory Improvement in 2005, Sherri was a welcome addition and has proven herself to be a knowledgeable and invaluable asset to North Carolina Public Health laboratories. As a medical technologist possessing a wealth of clinical and teaching experience gained in hospital settings and her ASCP specialty certification in blood banking, Sherri has impressive credentials as a laboratory improvement consultant.

  But the attributes Sherri possesses that are not so readily captured on paper include her initiative, tireless pursuit of quality, excellent communication and reasoning skills, tact and diplomacy, and faithful support of colleagues and the local health department laboratories she serves.

  Sherri has advanced many of the activities in which Laboratory Improvement is involved, including our collaboration with the Communicable Disease Branch in its Get Real, Get Tested campaigns. Sherri was instrumental this year in formulating checklists to guide the laboratory-related activities of these events, while fine-tuning the workflow and processes with members of the HIV/STD Branch. Sherri also regularly participates with HIV/STD on local health department assessments scheduled within her region of service.

  Sherri has previously served as a CPT coding resource within Laboratory Improvement for laboratory test methods and maintaining policies and protocols for our NC CLIA Contract Program. In addition to her duties as the Technical Consultant for her CLIA contract counties, Sherri willingly assumes additional responsibilities, including event coordinator for the 2008 Clinical Laboratory Day conference, and as an officer for the NCPHA Laboratory Section.

Welcome Dr. Keller!

The newest member of the management team at the North Carolina State Laboratory of Public Health is David E. Keller, PhD CHE. He began as the Assistant Laboratory Director in August 2009.

Dr. Keller's post-secondary education began at Auburn University, where he graduated with a Bachelor's of Science in Chemical Engineering with a minor in Biochemistry, followed by a PhD in BioChemical Engineering at North Carolina State University. His thesis work involved experimental derivatization and characterization of High Pressure Liquid Chromatography supports.

He also has an industry background in the areas of pharmaceuticals and medical diagnostics. Specifically, he held various scientific and leadership positions at Organon-Teknika (now bioMerieux) for 14 years developing and manufacturing various *in vitro* diagnostic assays in the areas of Immunology/Virology, Clinical Microbiology, and Hemostasis. More recently he held engineering, consulting and leadership positions in the pharmaceutical industry with Biogen-Idec and Glaxo Smith Kline.

During this period, he developed expertise with Regulated Quality Systems (Food and Drug Administration, European Medicines Agency, International Standards Organization, and International Committee on Harmonisation standards), Validation (methods, instrumentation, manufacturing processes, computer systems, control systems, cleaning processes), Structured Development Processes, Quality by Design, and Project Management in addition to the more traditional engineering/scientific expertise associated with Pharmaceutical and Medical Diagnostic manufacturing. He also has significant scientific customer service experience through providing solutions to assay and laboratory issues for the American Red Cross blood banking system.

nc department of health and human services

North Carolina Public Health

State of North Carolina • Beverly Eaves Perdue, Governor
Department of Health and Human Services • Lanier M. Cansler, Secretary
Division of Public Health • www.ncdhhs.gov

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